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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/500,334

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Mitsuru Maeda

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8952

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7590

02/13/2008

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EXAMINER

MCINTOSH III, TRAVIS C

ART UNIT

PAPER NUMBER

1623

MAIL DATE

DELIVERY MODE

02/13/2008

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

### Office Action Summary

**Application No.**

10/500,334

**Applicant(s)**

MAEDA ET AL.

**Examiner**

TRAVISS C. MCINTOSH III

**Art Unit**

1623

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 28 November 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1,8,9,11-15,21 and 26-30 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1,8,9,11,12,14,15,21,26,27 and 30 is/are rejected.
- 7) ☒ Claim(s) 13,28 and 29 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

### **DETAILED ACTION**

The Amendment filed 11/28/2007 has been received, entered into the record, and carefully considered.

Remarks drawn to rejections of Office Action mailed 8/28/2007 include:

102(b) rejection: which has been overcome by applicant's arguments and has been withdrawn. Specifically, the disclosure of the beta form is seen to be a typographical error and thus based upon *In re Yale*, that typo teaching cannot anticipate the claimed subject matter.

103(a) rejection: which has been overcome for the same reasons as above.

An action on the merits of claims 1, 8, 9, 11-15, 21, and 26-30 is contained herein below. The text of those sections of Title 35, US Code which are not included in this action can be found in a prior Office action.

Based upon new art cited below, finality of the action mailed on 8/28/2007 is withdrawn.

### ***Claim Rejections - 35 USC § 101***

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claim 1 is rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. The claim does not state that the compound is not in isolated and/or purified form, thus it reads on a product of nature as it occurs in plant extracts such as a plant

from *Lycium genuse*. The process of extraction disclosed is not seen to change the compound structurally.

### ***Claim Objections***

Claim 12 is objected to because of the following informalities: the claim is an independent claim which starts with “The method”, and should begin with “A method”. Appropriate correction is required.

Claim 15 is objected to because of the following informalities: the claim is drawn to a composition “comprising the 2-O...” compound and the word “the” should be removed. Appropriate correction is required.

### ***Claim Rejections - 35 USC § 102***

Claims 1, 8, and 9 rejected under 35 U.S.C. 102(b) as being anticipated by JP 53098954.

The '954 patent discloses 2-O-( $\beta$ -D-glucopyranosyl)-L-ascorbic acid (see page 6, 2<sup>nd</sup> paragraph). The '954 patent also teaches to protect the sugar hydroxyl groups with acetyl groups (see page 9, 2<sup>nd</sup> full paragraph). It is noted that in applicants specification they discuss the '954 patent, and state that the '954 patent provides no concrete production examples, and that even if the compounds were synthesized by the '954 method, the 3-hydroxyl would also be glycosylated leading to a diglucoside with sugars at the 2- and 3-positions. However, on page 10 of the document they discuss protecting the 3-position hydroxyl to obtain a compound which is only has the sugar bonded to the 2-position of the ascorbic acid, thus producing the instantly claimed

compound. The '954 patent also teaches their compound has vitamin C activity (see last paragraph on page 11).

***Claim Rejections - 35 USC § 103***

Claims 1, 8, 9, 11-12, 14-15, 21, 26-27, and 30 rejected under 35 U.S.C. 103(a) as being unpatentable over JP 53098954 as applied to claims 1, 8, and 9 above, and further in view of Sakai et al. (US 5,407,812 of record).

Claim 1 is drawn to a 2-O- $\beta$ -D-glucopyranosyl-L-ascorbic acid compound. Claims 8 and 9 provide the saccharide comprises acetyl groups in the 2', 3', 4', and 6'-positions of the sugar. Claims 11 and 12 are drawn to methods of making the product using a glucosyltransferase. Claims 14-15, 21, 26-27, and 30 are drawn to various forms of compositions comprising the active agent.

The '954 patent teaches 2-O-( $\beta$ -D-glucopyranosyl)-L-ascorbic acid (see page 6, 2<sup>nd</sup> paragraph) and to protect the sugar hydroxyl groups with acetyl groups (see page 9, 2<sup>nd</sup> full paragraph) as set forth supra. What is not taught is to make with a saccharide transferring enzyme (glucosyltransferase) nor compositions comprising the same.

Sakai et al. teach to make their glucopyranosyl ascorbic acid compounds using a saccharide-transferring enzyme (see paragraph bridging columns 3 and 4). Sakai et al. teach that an amount of 0.001% or more of their alpha derivative is acceptable for use (see column 8, lines 33-48). Sakai et al. also teach that their composition may be used in various forms, such as cosmetic, pharmaceutical, or dietary uses (see column 9, lines 49-61).

It would have been obvious to one of ordinary skill in the art at the time of the invention to use the saccharide transferring enzymes of Sakai et al. to make the compounds of the '954 patent. Sakai et al. teach methods of making their compounds using L-ascorbic acid and their  $\alpha$ -glucosyl saccharide and a saccharide-transferring enzyme. As such, it would be obvious to make the  $\beta$ -derivatives as instantly claimed with the methods of making the  $\alpha$ -glucosyl derivatives in the art merely by using a  $\beta$ -derivative as a starting compound instead of the art taught  $\alpha$ -glucosyl compound, as well as using a  $\beta$ -transferase. Moreover, the fact that applicants obtained compositions comprising both 2-O and 6-O derivatives is seen to be inherent within the methods taught. That is, since the methods claimed are seen to be obvious, and the 6-O derivative is produced by the obvious method, the method of making the mixture, as well as the mixture, is also seen to be obvious. moreover, the '954 patent teaches the beta-derivative derivative instantly claimed, as well as teach the compound has vitamin C activity, as set forth supra. It is well established that a composition (composition plus carrier) is allowable only if no utility is disclosed for the old compound and the '954 patent teach that their compounds are vitamin C derivatives. See *Ex parte Erdmann*, 194 USPQ 96. or *Ex parte Dourous*, 163 USPQ 667 (PTO Bd. App. 1968).

### *Conclusion*

Claims 13, 28, and 29 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to TRAVISS C. MCINTOSH III whose telephone number is (571)272-0657. The examiner can normally be reached on M-F 9:30-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shaojia A. Jiang can be reached on 571-272-0627. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Traviss C. McIntosh III  
February 11, 2008  
Art Unit 1623

/Traviss C. McIntosh III/